

**REMARKS**

The Office Action of August 11, 2005, has been received and reviewed.

Claims 1-22 are currently pending and under consideration in the above-referenced application. Of these, claims 1-16 and 18-22 stand rejected. Claim 17 is directed to subject matter that is “free of the prior art.”

Reconsideration of the above-referenced application is respectfully requested.

**Rejections under 35 U.S.C. § 102**

Claims 1-3, 7-16, and 18-22 stand rejected under 35 U.S.C. § 102(b) for being directed to subject matter that is purportedly anticipated by the subject matter described in U.S. Patent 5,080,895 to Tokoro (hereinafter “Tokoro”).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

The description of Tokoro is limited to exposing a chicken to antigens (*i.e.*, the 987P, K88, and K99 antigens of enterotoxigenic *E. coli* (ETEC)) that purportedly result in the presence of a “transfer factor-like component” in eggs that are laid by the chicken. Col. 5, lines 4-6; col. 5, lines 14-22; col. 5, line 29, to col. 6, line 7. A “transfer factor-like component” is not transfer factor. *See* Dunnick, W., et al., “Lack of Antigen Fragments in Guinea Pig Transfer Factor-like Activity, *Clin. Immunol. And Immunopathol.* 17: 55-65 (1980), at page 65, a copy of which is enclosed for the sake of convenience.

Further, although a “transfer factor-like” substance, such as the “unknown food factor” described in U.S. Patent 4,402,938 to Collins et al. (*see, e.g.*, Tokoro, col. 7, lines 51-53) or nucleosides, which have molecular weights of less than about 2,000 Da, may cause a non-specific improvement in treated animal’s immune system response that could be viewed superficially as similar to the way that immune system would respond to transfer factor, these

and other “transfer factor-like” substances are incapable of causing the immune system of a treated animal to elicit a specific response (*i.e.*, a response to a particular antigen), while transfer factor can elicit a specific response from the immune system of a treated animal.

In any event, Tokoro indicates that “transfer factor-like” substance described therein is not transfer factor. Specifically, Tokoro provides that “the immunological functions of the transfer factor-like component . . . are not known” (col. 7, lines 44-47). As evidenced by much of the art that has been made of record in the above-referenced application, the immunological functions of transfer factor were, in contrast, known at the time the application that eventually issued as Tokoro was filed.

Therefore, Tokoro does not expressly describe a method for causing an animal to elicit a T-cell mediated immune response, including administering a composition including transfer factor to the animal, as required by independent claims 1 and 20.

Further, it has been asserted that “Tokoro’s chickens were undoubtedly exposed to a pathogen at some point before laying eggs that induced an immune response.” Office Action of August 11, 2005, page 2. This is an inherency argument. M.P.E.P. § 2112 explains inherency as follows:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) . . . ‘To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill . . .’ *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1991).

Thus, in order for Tokoro to inherently describe a composition that includes an extract that comprises transfer factor, transfer factor *must* have been present in eggs that were collected in Tokoro. That means that the chickens from which eggs are collected, or the eggs themselves, must have been exposed to antigens that would cause a T-cell mediated immune response.

There are at least two reasons that transfer factor is not inherently present in eggs that are collected in accordance with the teachings of Tokoro. First, the 987P, K88, and K99 antigens of ETEC are known to elicit a B-cell response, which would not result in the presence of transfer factor in the collected eggs, without eliciting a T-cell response, which would result in the presence of transfer factor in the collected eggs. Macpherson, A.J., et al., "A Primitive T Cell-Independent Mechanism of Intestinal Mucosal IgA Responses to Commensal Bacteria," *Science*, 28: 2222-2226 (2000); Song, M-K, et al., "Light Chain of Natural Antibody Plays a Dominant Role in Protein Antigen Binding," *Biochem. and Biophysical Res. Communications*, 268:390-394 (2000); Aramaki, M., et al., "Presence of Activated B-1 Cells in Chronic Inflamed Gingival Tissue," *J. Clin. Immunol.*, 18: 421-429 (1998); Hansen, P.G.C., et al., "The Occurrence and Sources of Natural Antibody in Human Bile and Serum Against the O Antigens of Two *Escherichia coli* Serotypes," *Scand. J. Immunol.*, 32:537-544 (1990); Galili, U., et al., "Interaction between Human Natural Anti- $\alpha$ -Galactosyl Immunoglobulin G and Bacteria of the Human Flora," *Infection and Immunity*, 56:1730-1737 (1988); Skarnes, R.C., "Humoral Bactericidal Systems: Nonspecific and Specific Mechanisms," *Infection and Immunity*, 19:515-522 (1978); Sewell, H.R., et al., "The natural antibody response to *E. coli* includes antibodies of the IgD class," *Clin. Exp. Immunol.*, 31:104-110 (1977), copies of each of which are enclosed.

Further, Tokoro does not expressly or inherently describe that chickens must be exposed to any other antigens. In fact, Tokoro notes, at col. 2, lines 54-60, that animals may be "germ-free," as is well-known in the art. Stated another way, chickens that are born, raised, and housed in controlled (*e.g.*, sterile or otherwise "germ-free") environments could be exposed only to one or more of the three antigens disclosed in Tokoro, without being exposed to any antigens that would cause the chickens to elicit a T-cell mediated immune response. The Office has already acknowledged this possibility by stating, "[u]nless Tokoro housed the chickens in a completely sterile environment, one would expect that Tokoro's chickens had had a T-cell immune response to some antigen." Office Action of August 11, 2005, pages 2-3. Tokoro does not provide any indication about whether the chickens were raised in a sterile environment or a non-sterile environment. As the chickens described in Tokoro could have been raised in a sterile

environment, Tokoro does not inherently describe that chickens were exposed to antigens that would cause a T-cell mediated immune response. Therefore, it is not inherent that transfer factor would have been present in eggs laid by the chickens described in Tokoro.

Due to the possible lack of a T-cell mediated immune response, any eggs collected from the chickens would not include necessarily transfer factor in a quantity adequate for transferring cellular immunity to a mammal *in vivo*. Thus, compositions that include extracts of the eggs could not necessarily, or inherently, be used in a method in which a T-cell mediated immune response is initiated in a treated animal.

As such, it is clear that the description of Tokoro does not anticipate each and every element of either independent claim 1 or independent claim 20, as would be required to maintain the 35 U.S.C. § 102(b) rejections of independent claims 1 and 20.

Claims 2, 3, 7-16, 18, 19, and 22 are each allowable, among other reasons, for depending directly or indirectly from claim 1, which is allowable.

Claim 19 is additionally allowable since Tokoro includes no express or inherent description that there is a sufficient amount of transfer factor in any of the compositions disclosed therein to cause an animal to which the composition is administered to elicit a T-cell mediated immune response *in vivo*.

Claim 22 is further allowable since Tokoro lacks any express or inherent description that administration of an extract of the eggs disclosed therein to a treated animal would enhance the ability of the immune system of the treated animal to elicit an increased T-cell mediated immune response relative to the treated animal's normal T-cell mediated immune response to at least one antigenic agent.

Claim 21 is allowable, among other reasons, for depending directly from claim 20, which is allowable. Claim 21 is also allowable since Tokoro includes no express or inherent description that there is a sufficient amount of transfer factor in any of the compositions disclosed therein to cause an animal to which the composition is administered to elicit a T-cell mediated immune response *in vivo*.

**Rejections Under 35 U.S.C. § 103(a)**

Claims 4-6 have been rejected under 35 U.S.C. § 103(a) for being directed to subject matter that is allegedly unpatentable over the subject matter taught in Tokoro, in view of teachings from U.S. Patent 5,840,700 to Kirkpatrick et al. (hereinafter “Kirkpatrick”).

The standard for establishing and maintaining a rejection under 35 U.S.C. § 103(a) is set forth in M.P.E.P. § 706.02(j), which provides:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Claims 4-6 are each allowable, among other reasons, for depending directly from claim 1, which is allowable. Claims 4-6 are additionally allowable because, one of ordinary skill in the art would not have had the benefit of hindsight available to the Office, which is apparently the sole source of motivation for the assertion that one of ordinary skill in the art would have been motivated to combine teachings relating to obtaining transfer factor from mammalian tissues (Kirkpatrick) with teachings that relate to the presence of a non-transfer factor, transfer factor-like substance in eggs (Tokoro).

Moreover, one of ordinary skill in the art wouldn’t have been motivated to combine teachings from Tokoro and Kirkpatrick since the teachings of Kirkpatrick may be effectively administered non-orally, as they include transfer factor that is very pure, while the compositions of Tokoro may not be effective when administered non-orally, since they are intended to treat intestinal pathogens and, further, since one of ordinary skill in the art would readily recognize that the “purification” processes described in Tokoro would not remove large molecules such as antibodies from the resulting compositions.

Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejections of claims 4-6 is respectfully solicited.

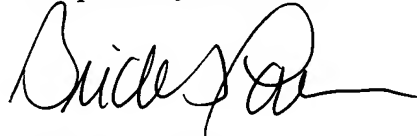
**Allowable Subject Matter**

The indication that claim 17 is drawn to subject matter that is allowable over the art of record is noted with appreciation. Claim 17 has not been amended to independent form, however, as claim 1, from which it depends, is believed to be allowable.

**CONCLUSION**

It is respectfully submitted that each of claims 1-22 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Brick G. Power", with a long horizontal flourish extending to the right.

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